

EXHIBIT

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AMERICAN FEDERATION OF STATE,	:	
COUNTY AND MUNICIPAL EMPLOYEES,	:	
DISTRICT COUNCIL 47 HEALTH AND	:	
WELFARE FUND, ET AL.,	:	CIVIL ACTION NO. 09-431
Plaintiffs,	:	
	:	
	:	
	:	
CEPHALON, INC.,	:	
Defendant.	:	

Defendant Cephalon is a pharmaceutical company that manufactures and sells several prescription drugs, including Provigil and Gabitril. Compl. ¶ 7. Provigil is a prescription drug approved by the United States Food and Drug Administration (“FDA”) to treat excessive daytime sleepiness associated with narcolepsy. Compl. ¶ 23. Gabitril is an FDA approved anti-epilepsy drug indicated as adjunctive therapy for

adults and children twelve (12) years of age or older in the treatment of partial seizures. Compl. ¶ 25.

Plaintiffs contend that because Defendant was aware that the market potential for Provigil and Gabitril was limited, Defendant engaged in an unlawful marketing scheme to promote off-label uses of these drugs. Plaintiffs argue that Defendant sought to accomplish this by providing financial incentives to physicians that constituted kickbacks for prescribing and speaking in favor of unapproved uses, as well as doubling its sales force between 2001 and 2002. Compl. ¶¶ 28-31. Plaintiffs further allege that Defendant pays its speakers one thousand, five hundred (\$1500) per lecture and hosts lectures at attractive locations, along with smaller programs at high-end restaurants. Compl. ¶¶ 47-50. According to Plaintiffs, while presentations note some side effects of these drugs, more serious side effects and severe results from various studies are falsely omitted. Compl. ¶¶ 54-55. Plaintiffs note that the FDA reprimanded Defendant for dissemination of false or misleading materials on the drug Provigil, and that the FDA required Defendant to add a bolded warning on the Gabitril label advising doctors of the association between Gabitril and seizures in non-epileptic patients. Compl. ¶¶ 42, 45. Consequently, Plaintiffs claim that Defendant has improperly promoted the medically unnecessary use of Provigil and Gabitril, which resulted in improper billing to Plaintiffs. Compl. ¶¶ 46.

In response, Defendant relies on this Court's May 22, 2009 decision where it concluded that the allegations in the complaint captioned *In Re Actiq Sales and Marketing Practices Litigation* were insufficient to establish a structure for the RICO enterprise that the Actiq plaintiffs alleged was created to promote the drug Actiq for medically unnecessary uses. After granting Defendant's Motion for Judgment on the Pleadings, the Court consolidated the Actiq complaint with the AFSCME complaint. Defendant now argues that the RICO counts in the AFSCME complaint should be dismissed for the same reasons, namely that the two complaints are virtually identical, and therefore the allegations in the AFSCME complaint must also be found insufficient to establish a structure for a RICO enterprise.

LEGAL STANDARD

A motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) is subject to the same standard of review applicable to a motion to dismiss under Rule 12(b)(6). *See Turbe v. Gov't of Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991). In considering a motion to dismiss under Rule 12(b)(6), the Court must accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, viewing them in the light most favorable to the plaintiff. *Taliaferro v. Darby Twp. Zoning Bd.*, 458 F.3d 181, 188 (3d Cir. 2005). A Rule 12(b)(6) motion should be granted only if it appears to a certainty that no relief could be granted under any set of facts that could be proved. *Id.*

Thus, the allegations in the complaint must transcend the speculative, and instead, state a claim to relief that is plausible on its face. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556 (2007) Applying the plausibility standard, a court may accept as true only well-pleaded allegations, which does not include bald assertions or legal conclusions. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 2007). When evaluating allegations, a court must determine whether the allegations are well-pleaded allegations, such that the allegations are more than “merely consistent with a defendant’s liability.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009). Essentially, the allegations in the complaint must “raise a right to relief above the speculative level,” and state a claim that is plausible on its face. *Twombly*, 550 U.S. at 555. “The issue is not whether a plaintiff will ultimately prevail but whether he or she is entitled to offer evidence to support the claims.” *Oatway v. Am. Int’l Group, Inc.*, 325 F.3d 184, 187 (3d Cir. 2003).

DISCUSSION

18 U.S.C. § 1962(c) makes it unlawful for any person employed by or associated with any enterprise to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity. In order to state a RICO claim under 18 U.S.C. § 1962, a plaintiff must first demonstrate statutory standing under RICO. A civil RICO plaintiff is required “to make two related but analytically distinct threshold showings: (1) that the plaintiff suffered an injury to business or property; and (2) that the

A RICO enterprise is defined as “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4). To establish the existence of an enterprise, or an association-in-fact enterprise, a plaintiff must show evidence of an ongoing organization, formal or informal; evidence that the various associates of the enterprise function as a continuing unit; and evidence that the enterprise has an existence separate and apart from the pattern of activity in which it engages. *United States v. Ricobene*, 709 F.2d 214, 221 (3d Cir. 1983).

Under the rules of notice pleading, a plaintiff need not specifically allege all of the facts necessary to

establish these three enterprise elements in the complaint. *Seville Indus. Mach. Corp. v. Southwest Mach. Corp.*, 742 F.2d 786, 790 (3d Cir. 1984). However, the allegations of the complaint must not affirmatively negate any of these elements. *Id.* at 790. Further, there must be sufficient allegations to allow the existence of the three elements to be inferred. *See Lorenz v. CSX Corp.*, 1 F.3d 1406, 1412 (3d Cir. 1991).

Relying on *Boyle v. United States*, 129 S. Ct. 2237 (2009), Defendant argues that Plaintiffs have not provided sufficient allegations of an organizational structure for the alleged enterprise. In response, Plaintiffs emphasize the *Boyle* Court's holding that while an association-in-fact enterprise must have a structure, it is not required to have a structure beyond that inherent in the pattern of racketeering activity in which it engaged. *Boyle*, 129 S. Ct. at 2244-46.

According to the *Boyle* Court, "an association-in-fact enterprise must have at least three structural features: a purpose, relationships among those associated with the enterprise, and longevity sufficient to permit these associates to pursue the enterprise's purpose." *Boyle*, 129 S. Ct. at 2244. While the *Boyle* Court reiterated certain principles established in *United States v. Turkette*, 452 U.S. 576, 583 (1981), namely that "the existence of an enterprise is an element distinct from the pattern of racketeering activity and that proof of one does not necessarily establish the other," it noted the recognition in *Turkette* that "the evidence used to prove the pattern of racketeering activity and the evidence establishing an enterprise may in particular coalesce." Specifically, the *Boyle* Court found that the language in the RICO statute was not intended to mean that "the existence of an enterprise may never be inferred from the evidence showing that persons associated with the enterprise engaged in a pattern of racketeering activity."

Using the *Boyle* Court's reasoning, Plaintiffs argue that their complaint sets forth sufficient allegations to establish the three structural features necessary for an association-in-fact, and that a hub and spoke organizational, decision-making structure is visible, or can be inferred. This Court finds Plaintiffs' arguments persuasive.

Plaintiffs' complaint provides allegations which identify the structure in question in more than vague terms, as well as particular members of the enterprise and details regarding the actual operation of the

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